UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

A.F., an infant by and through her mother and natural guardian Yael Fogel, and YAEL FOGEL, individually,

Plaintiffs,

– against –

SORIN GROUP USA, INC., CARBOMEDICS, INC., SORIN GROUP CANADA, INC., and JOHN DOE MANUFACTURING COMPANIES AND/OR CORPORATIONS 1 THROUGH 10, whose names are unknown at this time who manufactured, designed, produced, sold, or distributed the Mitroflow LXA19 Aortic Pericardial Heart Valve and all its component parts used during the August 5, 2013 surgery performed on the infant plaintiff,

Defendants.

OPINION AND ORDER

17 Civ. 5903 (ER)

Ramos, D.J.:

This case is about a young child who received a prosthetic heart valve that failed and had to undergo surgery to replace it, during which she suffered a stroke, partial paralysis, and seizures. The infant, A.F., and her mother, Yael Fogel (collectively, "Plaintiffs"), brought this diversity action against Sorin Group USA, Inc.; CarboMedics, Inc.; and Sorin Group Canada, Inc. (collectively, "Defendants")[1] for injuries allegedly caused by the prosthetic Mitroflow Aortic Pericardial Heart Valve (the "Valve") that failed. Defendants have moved to dismiss the Complaint for failure to state a claim upon which relief can be granted pursuant to Federal Rule of Civil Procedure 12(b)(6). For the reasons set forth below, Defendants' motion to dismiss is GRANTED IN PART and DENIED IN PART.

[1] Defendant Sorin CRM USA, Inc. was voluntarily dismissed on January 24, 2018. Doc. 28.

I. Background[2]

Defendants are the manufacturers, sellers, and distributors of the Valve, which is a Class III medical device regulated by the Food and Drug Administration ("FDA") under the Medical Device Amendments of 1976 ("MDA").[3] Compl. ¶ 48, Doc. 1. In late 2006 and through 2007, Defendants submitted an application and several amended applications for premarket approval of the Valve, which is the process by which the FDA evaluates the safety and effectiveness of Class III medical devices. *Id.* ¶ 49–50. As part of that process, Defendants submitted numerous types of information, including details on the device's components and manufacturing process, proposed indications for use that listed "no contraindications," and a clinical study of 699 patients that did not include any patients under the age of 27.[4] *Id.* ¶¶ 4, 14, 51.

In October 2007, the FDA conditionally approved the Valve for commercial distribution subject to a number of requirements, including reporting to the FDA instances of adverse effects of the device in patients. *Id.* ¶ 52. Pursuant to that conditional approval, Defendants began distributing the Valve. *Id.* ¶ 54.

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[2] The following facts are drawn from the allegations in the Complaint, which the Court accepts as true for purposes of the instant motion to dismiss. *See Koch v. Christie's Int'l PLC*, 699 F.3d 141, 145 (2d Cir. 2012). In addition, the Court may consider "documents . . . incorporated in [the Complaint] by reference" and "matters of which judicial notice may be taken." *Wilson v. Merrill Lynch & Co.*, 671 F.3d 120, 123 (2d Cir. 2011) (quoting *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002)).

[3] "The devices receiving the most federal oversight are those in Class III, which include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008).

[4] Although the Valve was not contraindicated for pediatric patients, Defendants note that the Valve's label stated the following under "WARNINGS AND PRECAUTIONS": "Clinical experience described in the medical literature suggests that juvenile patients or patients . . . who are 55 years of age or less may experience accelerated calcification of bioprosthetic heart valves." Defs.' Mem. Ex. B., Doc. 18-3. The Court may consider the warning label because it is referenced in the Complaint and is an FDA-approved document. *See Roth v. Jennings*, 489 F.3d 499, 509 (2d Cir. 2007) ("Documents that are . . . incorporated in [the complaint] by reference are deemed part of the pleading and may be considered."); *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 575–76 (E.D.N.Y. 2012) (taking judicial notice of FDA-approved warning labels).

After its release, some patients who received the Valve experienced symptoms of valve deterioration and malfunction of the "leaflets," a component of the Valve that controls the flow of blood, as has been documented in medical and scientific literature. *Id.* ¶¶ 73, 75. In the spring of 2013, a child died after her Valve, implanted two years earlier, was severely obstructed and deteriorated due to excessive calcification. *Id.* ¶ 75.

Plaintiffs allege that upon learning of these adverse events, Defendants failed to timely report the information to the FDA and attempted to conceal it. *Id.* ¶¶ 9–11. For example, Plaintiffs allege that Defendants followed up on only a small number of 211 adverse event reports that they received, deflected blame for most of these adverse events, delayed production of adverse event reports to the FDA, and submitted insufficiently detailed annual reports that minimized problems. *Id.* ¶ 89.

Nonetheless, Plaintiffs allege that the evidence of Valves prematurely failing led Defendants to seek to change the product, and ultimately to discontinue the previous version. *Id.* ¶¶ 2, 72, 74. On July 1, 2013, Defendants applied to the FDA to change the Valve's manufacturing process to include an anticalcification treatment called phospholipid reduction treatment. *Id.* ¶¶ 64–65. On April 18, 2014, the FDA approved these changes to the Valve. *Id.* ¶¶ 66–67.

A.F. is an infant born with cardiac birth defects. *Id.* ¶ 5. On August 5, 2013, about a month after Defendants applied to change the Valve but before the new version was approved, A.F. underwent surgery at New York Presbyterian Columbia University Medical Center to replace her pulmonary heart valve with the Valve. *Id.* ¶¶ 5, 59–60. Because the implanted Valve was the prior version, it did not have the anticalcification treatment. *Id.* ¶ 60, 68.

Two years later, A.F.'s Valve prematurely failed due to deterioration and stiff leaflets that obstructed the flow of blood, causing drops in the level of oxygen in her blood. *Id.* ¶¶ 70–71.

Although these conditions increased the risk of surgical complications, on November 16, 2015, A.F. again underwent surgery to replace the failing Valve. *Id.* ¶¶ 70, 77. A.F. suffered complications, including a bilateral stroke causing partial paralysis of the left side of her body and seizures, resulting in permanent physical and mental injuries. *Id.* ¶¶ 5, 78.

On August 4, 2017, Plaintiffs filed the instant action, asserting claims for negligence, strict products liability, negligent failure to warn, and loss of A.F.'s services. *Id.* ¶¶ 80–143. Plaintiffs assert their state-law claims "only to the extent that they are parallel to and not different from or in addition to the requirements of federal law." *Id.* ¶ 16. On November 28, 2017, Defendants moved to dismiss the Complaint for failure to state a claim under Rule 12(b)(6). Doc. 18.

II. Legal Standard

When ruling on a motion to dismiss pursuant to Rule 12(b)(6), the Court must accept all factual allegations in the complaint as true and draw all reasonable inferences in the plaintiff's favor. *Wilson v. Merrill Lynch & Co.*, 671 F.3d 120, 128 (2d Cir. 2011). However, the Court is not required to credit legal conclusions, bare assertions, or conclusory allegations. *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 681, 686 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). "To survive a motion to dismiss, a complaint must contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Id.* at 678 (quoting *Twombly*, 550 U.S. at 570). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). The plaintiff must allege sufficient facts to show "more than a sheer possibility that a defendant has acted unlawfully." *Id.* If the plaintiff has not "nudged [her] claims . . . across the line from conceivable to plausible," the complaint must be dismissed. *Id.* at 680 (quoting *Twombly*, 550 U.S. at 570).

III. Discussion

The MDA, which amended the Federal Food, Drug, and Cosmetic Act ("FDCA"), imposed a regime of federal oversight on medical devices by the FDA. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). In doing so, the MDA expressly preempted certain state laws through the following provision:

> Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).[5]

In sum, "[s]tate requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." *Riegel*, 552 U.S. at 330 (quoting 21 U.S.C. § 360k(a)(1)). State "requirement[s]" subject to preemption include common-law causes of action for negligence and strict liability. *Id.* at 323–24 (alteration in original). Thus, in *Riegel*, the Supreme Court held that the MDA preempts "[s]tate tort law that requires a manufacturer's [devices] to be safer . . . than the model the FDA has approved." *Id.* at 325. By the same token, "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at 330 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)).

[5] "The exception contained in subsection (b) permits the FDA to exempt some state and local requirements from pre-emption." *Riegel*, 552 U.S. at 316.

In addition to the express preemption provision of § 360k, state claims can also be impliedly preempted based on a conflict with the FDA's enforcement authority. In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 351 (2001), the plaintiffs brought state claims asserting that a company made fraudulent representations to the FDA in violation of FDCA requirements in the course of obtaining approval to market a medical device. *Id.* at 343, 352. The Supreme Court held that "the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law."[6] *Id.* at 348. The Court explained that "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration," and the FDA uses this authority "to achieve a somewhat delicate balance of statutory objectives." *Id.* The Court held that this balance would be upset by state claims that "exist solely by virtue of the FDCA . . . requirements" rather than "traditional state tort law which had predated the federal enactments." *Id.* at 352–53.

Read together, "*Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption." *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). "The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Id.* (quoting *Riley*, 625 F. Supp. 2d at 777). In other words, the plaintiff's state-law claim must

[6] The Court relied in part on a different provision, 21 U.S.C. § 337(a), which provides that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." *Id.*; *see Buckman*, 531 U.S. at 349 n.4, 352.

"parallel[] a federal-law duty under the MDA" but also exist "independent[ly]" of the MDA. *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc).

With these principles in mind, the Court turns to Plaintiffs' state tort claims here, which assert or suggest theories of fraud, design defect, manufacturing defect, and failure to warn. *See* Compl. ¶¶ 2–4.

A. Fraud

As an initial matter, although the Complaint does not explicitly assert a fraud theory, the Complaint alleges that Defendants did not apprise the FDA of the Valve's risk to juvenile patients in its premarket approval application, because they submitted a clinical study that did not include any patients under the age of 27. Compl. ¶¶ 3–4. Defendants seek to dismiss any claims based on this theory. Defs.' Mem. 11–12, Doc. 18-1. In response, Plaintiffs appear to concede that they do not assert a claim of fraud in the premarket approval application or that the application should have been rejected. Pls.' Opp'n 1, 4, Doc. 31. Rather, the Complaint focuses on Defendants' "post-market duties and responsibilities." Compl. ¶ 2.

Because this fraud-on-the-FDA theory is precluded by *Buckman*, which the parties do not appear to dispute, the Court dismisses any claims to the extent they assert fraud in the premarket approval process. *See Buckman*, 531 U.S. at 348; *Plourde v. Sorin Grp. USA, Inc.*, No. 17 Civ. 10507 (ADB), 2018 WL 1542361, at *4 n.3 (D. Mass. Mar. 29, 2018) (holding, in a case concerning the same Valve product, that "claims alleging malfeasance during the premarket approval process are preempted").

B. Design Defect

To state a claim for defective design, the plaintiff must show that "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury."

Bertini v. Smith & Nephew, Inc., 8 F. Supp. 3d 246, 254 (E.D.N.Y. 2014) (quoting *Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 83 (S.D.N.Y. 2001)).

Plaintiffs allege that Defendants defectively designed the Valve, when they knew or should have known of an "alternative design and manufacturing process which addressed the risks of premature failure," namely, an anticalcification process. Compl. ¶¶ 2, 11. However, as Plaintiffs admit, the FDA approved the Valve without the anticalcification process in October 2007. Compl. ¶ 3. Plaintiff's challenge to the FDA-approved design of the Valve would impose state requirements that are "different from, or in addition to," the FDA's requirements, and is thus preempted by § 360k. *See Riegel*, 552 U.S. at 325 ("State tort law that requires a manufacturer's [devices] to be safer . . . than the model the FDA has approved disrupts the federal scheme . . . ."); *Bertini*, 8 F. Supp. 3d at 254 ("[A]n action based on state law that would require a manufacturer to design a device, which has already received [premarket] approval, in a manner that is safer than what the FDA requires would impose additional state safety requirements on the device, and therefore this claim would be preempted under § 360k.").

Accordingly, Plaintiffs' claims asserting that the Valve was defectively designed are dismissed.

C. Manufacturing Defect

To plead a claim for a manufacturing defect, the plaintiff must show that "a specific product unit was defective as a result of 'some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction,' and that the defect was the cause of plaintiff's injury." *Bertini*, 8 F. Supp. 3d at 257 (quoting *Colon*, 199 F. Supp. 2d at 85). "In other words, a manufacturing flaw exists when the unit in question deviates in quality and other performance standards from all of the other identical units." *Id.* (quoting *Colon*, 199 F. Supp. 2d at 85).

A claim for a manufacturing defect that deviates from the design approved and required by the FDA is "parallel" to and not preempted by § 360k. *See Bausch v. Stryker Corp.*, 630 F.3d 546, 553 (7th Cir. 2010) ("[C]laims for defective manufacture in violation of federal law are not expressly preempted by section 360k . . . ."); *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 155–56 (S.D.N.Y. 2011) (holding that manufacturing-defect claims alleging that a device was not manufactured in accordance with FDA requirements are not preempted).

Here, however, Plaintiffs have failed to plausibly allege a manufacturing defect that violated FDA requirements. In a conclusory fashion, Plaintiffs allege that the Valve implanted in A.F. "deviated from the manufacture specifications approved by the FDA" and "was manufactured with a material that was different from and deviated from the material . . . approved by the FDA." Compl. ¶ 101. But Plaintiffs do not explain what those differences were or otherwise show how the Valve or its materials deviated from the approved design.[7] Accordingly, Plaintiffs fail to plausibly allege a manufacturing-defect claim, which must be dismissed.

D. Failure to Warn

To state a claim for a manufacturer's failure to warn, "a plaintiff must demonstrate that the warning was inadequate and that the failure to adequately warn of the dangers . . . was a

[7] To be sure, "in the context of Class III medical devices, much of the critical information is kept confidential as a matter of federal law," including "[t]he specifications of the FDA's premarket approval documents," and "[f]ormal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim." *Bausch*, 630 F.3d at 558, 560. But even in *Bausch*, the plaintiff plausibly alleged a manufacturing defect because the defendants recalled a batch of device components due to "dimensional anomalies," the FDA inspected the manufacturing facility and found "numerous deficiencies [in the device's] manufacturing and inspection processes," the FDA issued a letter warning that the device was "adulterated due to manufacturing methods . . . not in conformity with industry and regulatory standards," and the device was ultimately recalled. *Id.* at 559. Plaintiffs have made no similar allegations here.

proximate cause of his or her injuries." *Bertini*, 8 F. Supp. 3d at 256 (quoting *Figueroa v. Bos. Sci. Corp.*, 254 F. Supp. 2d 361, 369–70 (S.D.N.Y. 2003)).

To the extent Plaintiffs claim that the Valve's warning label was inadequate because the Valve was not contraindicated for pediatric patients, that claim, like the design-defect claim, must fail because the warning was approved by the FDA. Compl. ¶¶ 3, 14. Requiring the inclusion of this contraindication would impose a state requirement that is "different from, or in addition to," the FDA's requirements in violation of § 360k. *See Riegel*, 552 U.S. at 329 ("[T]he MDA would pre-empt a jury determination that the FDA-approved labeling for a [device] violated a state common-law requirement for additional warnings."); *Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 250 (S.D.N.Y. 2013) ("[T]he FDA's premarket approval established the information [defendant] was obligated to disclose.").

However, the core of Plaintiffs' failure-to-warn claim is that Defendants failed to timely and properly report information to the FDA concerning adverse effects of the product in violation of FDA requirements. *See, e.g.*, Compl. ¶¶ 10, 89 (alleging that Defendants delayed production of adverse event reports to the FDA, failed to follow up on many adverse event reports that they received, erroneously blamed most adverse events on other causes, and submitted insufficiently detailed annual reports that minimized problems); 21 C.F.R. §§ 814.82, 814.84 (providing that the FDA may require such reports). Numerous courts have held that state claims for violations of FDA reporting requirements are "parallel" to and thus not preempted by the MDA. *See Stengel*, 704 F.3d at 1232–33 (holding that a state claim for "failure to warn the FDA," "insofar as the state-law duty parallels a federal-law duty under the MDA, is not preempted"); *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 776 (5th Cir. 2011) ("[Plaintiff's]

failure to warn claim is neither expressly nor impliedly preempted by the MDA to the extent that this claim is premised on [defendant's] violation of FDA regulations with respect to reporting [adverse events] caused by the [device]."); *Plourde*, 2018 WL 1542361, at *7 (holding, with respect to the same Valve product, that "a state-law claim for failure to report information to the FDA is not preempted"); *Gale*, 989 F. Supp. 2d at 251 (holding that a state tort claim based on a failure to comply with a premarket approval's monitoring and reporting requirements is not preempted).

Since a state claim for failure to warn the FDA is not preempted, the next question is whether, under New York law, the duty to warn may include warning the FDA. *See Plourde*, 2018 WL 1542361, at *7 ("[T]he preemption analysis in this area turns on whether a particular state's common law requires the manufacturer to report information to the FDA . . . ."). Apparently no state or federal appellate courts in New York have addressed this question, and lower courts are split. *Compare Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170, 185 (N.D.N.Y. 2014) (holding that New York law imposes a continuous duty to exercise reasonable care in warning the FDA), *with Pearsall v. Medtronics, Inc.*, 147 F. Supp. 3d 188, 201 (E.D.N.Y. 2015) (holding that the New York duty to warn the medical profession does not include a duty to report to the FDA).

The Court agrees with Judge Kahn's decision in *Rosen*. Under New York common law, a "manufacturer of a product used by the medical community has a duty to warn the medical community 'of all potential dangers which it knows or should know, and must take such steps as are reasonably necessary to bring that knowledge to the attention of the medical [community].'" *Clar v. Riegler*, 849 N.Y.S.2d 739, 740 (App. Div. 4th Dep't 2007) (alteration in original) (quoting *Glucksman v. Halsey Drug Co.*, 553 N.Y.S.2d 724, 726 (App. Div. 1st Dep't 1990)). "This duty is a continuous one, and

requires that the manufacturer be aware of the current information concerning the safety of its product." *Krasnopolsky v. Warner-Lambert Co.*, 799 F. Supp. 1342, 1345–46 (E.D.N.Y. 1992) (citing *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 91 (2d Cir. 1980)). Moreover, New York courts have long recognized that the violation of a regulation mandating a standard of conduct is some evidence of negligence and probative of whether the conduct is reasonable and adequate under the circumstances. *E.g.*, *Rizzuto v. L.A. Wenger Contracting Co.*, 693 N.E.2d 1068, 1072 (N.Y. 1998). Courts have also recognized that the violation of MDA requirements can support claims for negligence and strict liability for a manufacturing defect. *Gelber*, 788 F. Supp. 2d at 155–57. Accordingly, the Court holds that a manufacturer's duty to take steps that are reasonably necessary to warn the medical community may include warning the FDA as required by the MDA. To the extent Plaintiffs assert a claim for failure to warn the FDA, that claim is not preempted.[8]

Nor is this claim impliedly preempted under *Buckman*. This claim does not "exist solely by virtue of the FDCA disclosure requirements," but rather "rel[ies] on traditional state tort law." *Buckman*, 531 U.S. at 352–53. Plaintiffs' claim is "based on the underlying state duty to warn about the dangers or risks of [the] product" and thus survives *Buckman* preemption.[9] *Hughes*, 631 F.3d at 775.

[8] To the extent Plaintiffs assert claims for failure to warn parts of the medical community other than the FDA, such as healthcare providers, or consumers, Compl. ¶ 9, those claims are preempted because they are "different from, or in addition to," the MDA's requirements. *See Bertini*, 8 F. Supp. 3d at 256 ("Because plaintiffs fail to identify a federal requirement that defendant warn the public and health care professionals directly that its devices were defective, plaintiffs' 'failure to warn' theory of strict liability does not 'parallel' federal requirements.").

[9] The Court respectfully disagrees with the contrary conclusion of *Lake v. Kardjian*, 874 N.Y.S.2d 751 (Sup. Ct. Madison Cty. 2008), which held that claims for violations of the MDA for failure to report were

Having determined that a state claim for failure to warn the FDA is viable, the Court further holds that Plaintiffs have plausibly alleged such a claim. As noted above, Plaintiffs allege specific deficiencies in the timeliness and content of Defendants' reports to the FDA concerning the Valve's adverse effects and identify FDA regulations requiring such reports. *See, e.g.*, Compl. ¶¶ 10, 89; 21 C.F.R. §§ 814.82, 814.84. Plaintiffs further allege that Defendants knew of adverse events before A.F.'s surgery implanting the Valve in August 2013, and had Defendants properly reported that information to the FDA, the medical community, including A.F.'s doctor, would have known of more adverse events and not implanted the Valve, which later failed and injured her. Compl. ¶¶ 8, 75, 90–91. These allegations, which are presumed true at this juncture, are sufficient to plausibly allege that Defendants' warning was inadequate and caused her injuries. *See Stengel*, 704 F.3d at 1234 (Watford, J., concurring) ("To prevail, [plaintiffs] will ultimately have to prove that if [defendant] had properly reported the adverse events to the FDA as required under federal law, that information would have reached [plaintiff's] doctors in time to prevent his injuries."); *Rosen*, 41 F. Supp. 3d at 187 (holding that the plaintiff stated a claim where she alleged that the defendants' failure to report occurred during the relevant time period and, had they properly reported, the reports would have reached her physician and may have avoided her injuries).[10]

impliedly preempted. *Id.* at 755. There, the court did not recognize, and the plaintiff did not argue, that such a claim is "parallel" and not preempted when it is grounded in the state duty to warn. *See id.*

[10] Plaintiffs suggest another theory of causation based on counterfactual regulatory actions by the FDA. Compl. ¶¶ 10, 90. The theory is that if the Defendants had properly apprised the FDA of adverse events, particularly in pediatric patients, "the FDA could have required a more particularized warning concerning patients under 30" or taken other action that would have avoided the Valve's implantation. *Plourde*, 2018 WL 1542361, at *8. However, the Fifth Circuit has rejected causation based on regulatory actions the FDA would have taken absent the violation because it is "entirely speculative" and "could impermissibly allow the jury to question the FDA's decision to approve the device" and warning label. *Hughes*, 631 F.3d at 776 n.12. The Court declines to adopt this causation theory because the Complaint plausibly

E. CarboMedics, Inc.

Defendants have moved to dismiss CarboMedics, Inc. from the case on the grounds that it was merged into its parent company, Sorin Group USA, Inc., on January 1, 2010, and thereby ceased to exist. Defs.' Mem. 1 n.1. In support, they attach a State of Delaware Certificate of Ownership recording the merger of CarboMedics into Sorin Group USA. Defs.' Mem. Ex. A, at 2–4, Doc. 18-2.[11]

Under Rule 17(b), a corporation's "[c]apacity to sue or be sued is determined . . . by the law under which it was organized." Fed. R. Civ. P. 17(b). CarboMedics is a Delaware corporation. Compl. ¶ 25; Defs.' Mem Ex. A., at 2–3. "[U]nder Delaware law it is settled that the separate corporate existence of a constituent corporation ceases upon merger and the emerging corporation is the only corporation with capacity to be sued and process cannot be served on the constituent corporation." *Sevits v. McKiernan-Terry Corp. (N.J.)*, 264 F. Supp. 810, 811 (S.D.N.Y. 1966) (citing Del. Code Ann. tit. 8, § 259). Accordingly, CarboMedics must be dismissed. *See id.* at 812 (dismissing nonexistent corporations for improper service of process, lack of personal jurisdiction, and failure to state a claim).

IV. Leave to Amend

Plaintiffs have requested leave to amend their Complaint in the event that the Court dismisses their claims. Pls.' Opp'n 25. Rule 15 instructs courts to "freely give leave [to amend a pleading] when justice so requires." Fed. R. Civ. P. 15(a)(2). The Second Circuit has instructed

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alleges causation based on adverse event information that would have reached A.F.'s doctor absent the violation, as explained above.

[11] The Court takes judicial notice of the State of Delaware Certificate of Ownership. *See Goldman v. Barrett*, No. 15 Civ. 9223 (PGG), 2017 WL 4334011, at *1 n.3 (S.D.N.Y. July 25, 2017) (taking judicial notice of Pennsylvania Secretary of State records concerning corporate formation and dissolution), *aff'd*, 733 F. App'x 568 (2d Cir. 2018); *Chevron Corp. v. Salazar*, 807 F. Supp. 2d 189, 193 n.5 (S.D.N.Y. 2011) (taking judicial notice of a certificate of merger filed with the Delaware Secretary of State).

courts not to dismiss a complaint "without granting leave to amend at least once when a liberal reading of the complaint gives any indication that a valid claim might be stated." *Shabazz v. Bezio*, 511 F. App'x 28, 31 (2d Cir. 2013) (quoting *Shomo v. City of New York*, 579 F.3d 176, 183 (2d Cir. 2009)); *see also Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Secs., LLC*, 797 F.3d 160, 191 (2d Cir. 2015) (reaffirming the "liberal spirit" of Rule 15 (quoting *Williams v. Citigroup Inc.*, 659 F.3d 208, 214 (2d Cir. 2011))). As it is not clear that the opportunity to amend would be futile, Plaintiffs' dismissed claims are dismissed without prejudice.

V. Conclusion

Defendants' motion to dismiss is GRANTED with respect to any claims for fraud in the premarket approval process, design defect, manufacturing defect, and inadequate warning label. Additionally, Defendants' motion is GRANTED with respect to the dismissal of CarboMedics. Defendants' motion is DENIED with respect to Plaintiffs' claim for failure to warn the FDA. Plaintiffs may file an amended complaint, if at all, on or before **October 29, 2018**. The Clerk of the Court is respectfully directed to terminate the motion, Doc. 18.

It is SO ORDERED.

Dated: September 28, 2018
New York, New York

Edgardo Ramos, U.S.D.J.